

**Declaration of Conformity
in accordance with Regulation (EC) 1935/2004**

the manufacturer:
Ampri Handelsgesellschaft mbH
Benzstr. 16
21423 Winsen (Luhe)
Germany

confirms the conformity of article

01194 MED-COMFORT BLUE ULTRA 300

blue				
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disposable nitrile gloves, powderfree

with the rules of the
Regulation (EC) 1935/2004 - article 3, 5, 11, 15 and 17-, german feed and food code – LFGB,
Regulation (EC) 10/2011 and the german recommendation XXI and XXI/1. of the Federal Institute
for Risk Assessment (BfR).

Specification of the intended use or limitations

The above-mentioned article can be used safely in the preparation and treatment of food. In this process, they may be in direct contact with the following types of food for a short time:

all types				
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Restriction

The article is not suitable for the following types of food:

not applicable				
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The valuation basis for the glove-application is a surface-to-volume ratio of 8,4 dm² per 5kg food in accordance with the German BfR.

sensory evaluation

simulant solution	conditioning	testing	result
coconut oil	10 minutes 40°C	odour change	no changes
coconut oil	10 minutes 40°C	flavour change	no changes
water	10 minutes 40°C	odour change	no changes
water	10 minutes 40°C	flavour change	very slight changes

results of the overall migration

simulant solution	conditioning	overall migration mg/dm ²	limit mg/dm ²
acetic acid 3%	10 minutes 40°C	< 2,5 mg/dm ²	10 mg/dm ²
ethanol 95%	10 minutes 40°C	5,2 mg/dm ²	10 mg/dm ²
Isooctane	5 minutes 20°C	< 2,5 mg/dm ²	10 mg/dm ²
ethanol 10%	10 minutes 40°C	4,6 mg/dm ²	10 mg/dm ²

results of the specific migration

compound	simulant solution	Conditioning or other analytical methods	result	limit
Phthalates	ethanol 95%	10 minutes 40°C	not detected	
Formaldehyde	acetic acid 3%	10 minutes 40°C	not detected	3 mg/L
Primary aromatic amines	acetic acid 3%	10 minutes 40°C	not detected	< 10 µg/kg
1,3-butadiene	water	10 minutes 40°C	not detected	nicht feststellbar
Acrylonitrile	water	10 minutes 40°C	not detected	nicht feststellbar

Result total content

compound	simulant solution	Conditioning or other analytical methods	result	limit
Polycyclic aromatic hydrocarbons (PAH)	extraction with toluene	Ultrasonic extraction	not detected	0,2 mg/kg
Phthalates		LC-MS	not detected	
Cadmium		microwave digestion with sulphuric	< 1 mg/kg	100 mg/kg
Lead		microwave digestion with sulphuric	< 1 mg/kg	100 mg/kg
Nitrosamines	acetic acid 3%	10 minutes 40°C	not detected	1 µg/dm ³
Zinc		microwave digestion with sulphuric	3.400 mg/kg	30.000 mg/kg
1,3-butadiene		#NV	not detected	1 mg/kg

Examination of pigments ((for coloured items))

simulant solution	evaluation
acetic acid 3%	passed, no colour transition
olive oil	passed, no colour transition

regulation (EU) 2020/1245

heavy metals

simulant solution:	acetic acid 3%
conditioning:	10 minutes 40°C

evidence	concentration in mg/kg	limit in mg/kg food or food simulant
Aluminium	< 0,1	1
Antimony		
Arsenic		
Barium	< 0,1	1
Cadmium		
Chromium		
Cobalt	< 0,005	0,05
Copper	< 0,5	5
Europium		
Gadolinium		
Iron	< 5	48
Lanthanum		
Lead		
Lithium	< 0,1	0,6
Manganese	< 0,1	0,6
Mercury	< 0,01	0,01
Nickel		
Terbium		
Zinc	< 3	5



Testreport-no & institute:

**(25420)288-470616, Bureau Veritas
*FUFDPC2018-01682E, intertek
3698/91-2, Isega

When used as specified, the overall migration as well as the specific migration do not exceed the legal limits.

The examination was conducted in accordance with
Regulation (EC) No. 10/2011 (Annex V), including all current amendments and corrections.

The requirements for materials and raw materials of the Plastic Regulation (EC) No. 10/2011 is not applicable for elastomer-protective gloves.

regulation (EC) 2023/2006

The above article is manufactured in accordance with Good Manufacturing Practices (GMP), i.e. they are produced and controlled with the assurance of compliance with applicable regulations and quality standards.

Ingredients with limited use in food

„dual use substances“

not applicable

Name of the substance	Ref.-No. (CAS-EINECS-PM and/or E-No)	Limit value [mg/kg]

The traceability according to the regulation (EC) No. 1935/2004 is ensured by the batch number.

Winsen, 28.05.2023

This declaration of conformity has a validity until 28.05.2026

Rev. 00